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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/559,995	08/07/2007	Venkata-Rangarao Kanikanti	AH/Le A 36 780	4575

71285 7590 11/27/2009

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EXAMINER	
YEAGER, RAYMOND P	
ART UNIT	PAPER NUMBER
1651	

NOTIFICATION DATE	DELIVERY MODE
11/27/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/559,995	KANIKANTI ET AL.	
	Examiner	Art Unit	
	Raymond P. Yeager	1619	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 September 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 2* is/are pending in the application.

4a) Of the above claim(s) *2* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/08/2005; 08/07/2007; 05/15/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1 to 2 are pending.

Election/Restriction

Applicant's election of group 1, claim 1 in the reply filed on 09/08/2009 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claim 2 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected group, there being no allowable generic or linking claim. Election was made without traverse in the reply filed on 09/08/2009.

Note - Specification

The use of the trademarks has been noted within this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks

Claim Rejections - 35 USC § 103

The following is a quotation of 35 USC 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 6,004,582 (Publication date: 12/21/1999), hereafter referred to as the '582 publication, in view of US patent application publication 2003/0175326 (Publication

date: 09/18/2003; Filing date: 08/06/2002), hereafter referred to as the '326 publication, Gennaro, 1990 (Remington's Pharmaceutical Sciences, Chapter 89. Oral Solid Dosage Forms, pp. 1633-1665), and Federal Registry, 1997 (vol. 62(139) 38906-38907), hereafter referred to as FR 1997, as modified by Federal Registry, 1997 (vol. 64(171) 48295), hereafter referred to FR 1999.

Applicant claims a tablet comprising 20 to 45 percent enrofloxacin, 18 to 35 percent lactose, 5 to 10 percent microcrystalline cellulose, and 5 to 20 percent meat flavor.

Determination of the scope and content of the prior art - (MPEP 2141.01)

The '582 publication teaches a formulation comprising a therapeutic agent in a tablet ('582, column 4, line 63 to 66 and column 5, line 65 to column 6, line 10) and comprises microcrystalline cellulose and lactose (column 7, lines 38-49; column 9, lines 38-52; column 10, lines 58-67; and column 11, lines 34-46) and provides a working example comprising a therapeutic agent, lactose, and microcrystalline cellulose (columns 18-19, example 2). The '582 patent notes that a number of agents, such as antibacterial agents, are equivalents for formulation and recite enrofloxacin as one of the antibacterial substances ('582, column 13, lines 53 to column 14, line 14). Since the therapeutic agents and enrofloxacin are considered equivalent therapeutic agents for formulation purposes in the '582 patent, it would have been obvious to one of ordinary skill in the art to provide a tablet formulation comprising enrofloxacin, lactose, and microcrystalline cellulose (limitations in instant claim 1). The '582 publication also provides for the addition of flavoring to the formulation ('582, column 11, line 58 to column 12, line 11) and recites that the therapeutic agent is present at 0.1 to 99 percent of the formulation ('582, column 9, lines 28-37) and thus it would be obvious to one of ordinary skill in the art to optimize the therapeutic agent concentration per MPEP § 2144.05.II. The '582 patent teaches the active agent can be present at 0.1 to 99.9 percent weight in the core, about 9 to about 45 percent microcrystalline cellulose,), and about 42 percent lactose ('582, column 9, lines 28-37; column 15, line 60 to column 19, line 41; and column 20, lines 7-24).

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

The difference between the instant application and the '582 patent is that the '582 patent does not expressly teach a meat flavoring or the claimed concentrations of lactose (18 to 35 percent) and meat flavour (5 to 20 percent). This deficiency in the '582 patent is cured by the teachings of the '326 publication and Gennaro, 1990 and FR 1997 as modified by FR 1999. The '326 patent teaches the use of antibacterial therapeutics and antibiotics in tablet form for veterinary treatment and FR 1997 as modified by FR 1999 teaches enrofloxacin (BAYTRIL®) tablets for administration to canines (FR 1997, 38906, column 2 to page 38907, column 1 as modified by FR 1999, page 48295, columns 1-2) thus it would be obvious to one of ordinary skill in the art to provide a tablet formulation for canines comprising enrofloxacin, especially as the '326 patent teaches the incorporation of beef flavor into the tablets to improve voluntary acceptance by canines (noted below). The '326 publication teaches a palatable tablet ('326, page 2, paragraphs 13 and 18). The '326 publication teaches the drug is present at 5 to 95 percent of the formulation (page 16, paragraph 173), and 1 to 30 percent of a palatability improving agent ('326, pages 16-17, paragraph 179). Further, the '326 provide working examples of formulations preferred by canines comprising 1, 5, and 10 percent artificial beef flavor ('326, page 9, example 1, table 1, paragraphs 108-110). Gennaro, 1990 teaches that both lactose and microcrystalline cellulose are diluents used in tablet formulation and further disclose that 5 to 15 percent of microcrystalline cellulose is used as an excipient in direct compression formulas (page 1635, column 1, tablet ingredients to column 2, paragraph 4). Gennaro, 1990 also teaches direct compression wherein lactose in incorporated as a vehicle and provides working examples wherein lactose is present at about 10 to about 50 percent (page 1645, column 1, direct compression to page 1646, paragraph 4 and pages 1654-1656, working examples). Thus it would have been obvious to one of ordinary skill in the art to optimize the concentrations of ingredients per MPEP § 2144.05.II.

Finding of prima facie obviousness - Rational and Motivation - (MPEP 2142-2143)

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to provide a tablet comprising enrofloxacin, lactose,

microcrystalline cellulose, and flavoring agent as taught by the '582 patent and provide artificial beef flavor (i.e. meat flavor) as the flavoring agent as taught in the '326 publication and optimize the ingredients as taught by the '326 publication and Gennaro, 1990.

One of ordinary skill in the art would have been motivated to do this because the '326 publication teaches palatability improving agents such as artificial beef flavor increase the voluntary acceptance by canines ('326, page 9, paragraphs 108-110, and table 1), FR 1997 as modified by FR 1999 teaches enrofloxacin tablet for administration to dogs for management of diseases associated with bacteria susceptible to enrofloxacin (FR 1997, column 2, 580.812 item (2)), and Gennaro, 1990 teaches diluents such as lactose and microcrystalline cellulose affect the stability of the formulation (page 1635, column 1, paragraphs 2-4 and column 2, paragraph 3) and as such are considered result-effective variables which may be optimized per MPEP § 2144.05.II. In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

No claims are allowed; all claims are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RAYMOND P. YEAGER whose telephone number is (571) 270-7681. The examiner can normally be reached on Mon - Thurs 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (571) 272-0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

R.P.Y.

/Jean C. Witz/
Primary Examiner, Art Unit 1619